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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,317	07/15/2003	Yunping Li	BBRI-2008US01	7947
7590 Kevin M. Farrell Pierce Atwood Suite 350 One New Hampshire Avenue Portsmouth, NH 03801			EXAMINER SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER
			1614	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/18/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary

Application No.

10/620,317

Applicant(s)

LI ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' Response filed November 6, 2006 is acknowledged. Claims 1-11 remain under consideration.

Applicants have presented requests for a substitute title and Abstract. Accordingly, the objection to the disclosure is withdrawn.

Claims 1-3 and 5-10 were rejected in the last Office Action under 35 U.S.C. 102(b) as being anticipated by Nohara et al., Biochemical and Biophysical Research Communications. It was asserted Nohara teaches the administration of the MEK inhibitor PD98059 to cultured pregnant rat uterine cells obtained at day 21 before the onset of labor (preterm). Pretreatment of cells with this MEK inhibitor completely inhibited both oxytocin- and EGF-induced tyrosine phosphorylation of MAP kinase. See Figure 2A where PD98059 immediately inhibited the oxytocin-induced uterine contraction as compared to non-administration of the MEK inhibitor.

Applicants argue without the teaching of the element of a pregnant mammal, the Nohara reference cannot be anticipatory. Nohara did not use pregnant mammals, as was done in the pending application. Applicants additionally urge the Nohara reference does not inherently teach the pending claimed invention of delaying labor in a pregnant animal.

It is noted the present claims fail to recite "delaying labor." Further, on page 943 Nohara concludes the MAP kinase pathway has some role in oxytocin-induced pregnant rat uterine muscle contraction. Thus, Nohara's teaching includes the element of "a pregnant mammal." The rejection of record of claims 1-3 and 5-10 under 35 U.S.C. 102(b) is maintained for the reasons of record.

In the last Office Action claims 1-11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nohara et al., Biochemical and Biophysical Research Communications, in view of Oldenhof et al., Am. J. Physiology. It was asserted Nohara teaches the administration of the MEK inhibitor PD98059 to cultured pregnant rat uterine cells obtained at day 21 before the onset of labor (preterm). PD98059 inhibited the oxytocin-induced uterine contraction as compared to non-administration of the MEK inhibitor. Oldenhof teaches the inhibitors PD-98059 and U-0126 as exhibiting essentially equivalent activity with respect to MAPK inhibition, specificity to the ERK pathway and to their response to stretch (as that imposed on the uterine wall by a growing fetus). Oldenhof teaches a role for mechanical factors in the induction of MAPK activity in the pregnant myometrium.

Applicants again argue Oldenhof uses isolated small muscle cells and therefore does not supply the element of "a pregnant mammal" in claims 1 and 4. Further, Applicants urge the references do not suggest a motivation to combine or a reasonable expectation of success.

Applicants' arguments have been given careful consideration but are not found persuasive. The rejection of record of claims 1-11 under 35 U.S.C. 103 is maintained for the reasons of record.

In view of the combined teachings of Nohara and Oldenhof, one skilled in the obstetrical art would have been motivated to administer a MAPK inhibitor such as PD-98059 or U-126 to delay preterm uterine contractions. On page 943, Nohara concludes the MAP kinase pathway has some role in oxytocin-induced pregnant rat uterine muscle

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contraction. Thus, Nohara's teaching includes the element of "a pregnant mammal." The prior art references provide a strong expectation of success in delaying preterm uterine contractions because they teach an inhibition of preterm uterine contractions following the administration of PD-98059 and U-1026. These compounds inhibit the activity of the mitogen-activated protein kinase enzyme system. Both mechanical as well as biochemical factors that control uterine contractions in a pregnant rat model are taught by Nohara and Oldenhof. Motivation to combine references flows from Oldenhof's teaching of equivalence in the activities of PD-98059 and U-0126 as selective inhibitors for the ERK pathway.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire **THREE MONTHS** from the mailing date of this Action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this Final Action.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 11, 2006

Phyllis Spivack

Phyllis Spivack

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**PHYLLIS SPIVACK
PRIMARY EXAMINER**